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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,905	12/10/2004	Michael C. Heinrich	899-65892-02	4619
24197 7590 09/26/2007 KLARQUIST SPARKMAN, LLP 121 SW SALMON STREET SUITE 1600 PORTLAND, OR 97204			EXAMINER HOWARD, ZACHARY C	
			ART UNIT 1646	PAPER NUMBER
			MAIL DATE 09/26/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/517,905

Applicant(s)

HEINRICH ET AL.

Examiner

Zachary C. Howard

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 28 June 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-15 and 63-107 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-15 and 63-107 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☒ Other: Sequence Alignment #1

## **DETAILED ACTION**

### ***Status of Application, Amendments and/or Claims***

The amendment of 6/28/07 has been entered in full. Claim 2 is amended. Claims 16-62 are canceled, as well as the original claim that was inadvertently presented as a second claim 15. New claims 63-107 are added.

Claims 1-15 and 63-107 are pending in the instant application.

### ***Notes***

(1) New claim 89 depends from cancelled claim 31. For purpose of restriction, claim 89 has been treated as depending from claim 63.

(2) New Claim 103 depends from non-existent claim 1027. For purpose of restriction, claim 103 has been treated as depending from claim 102.

### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-10 and 107, drawn to variant PDGFRA polypeptides (including fragments), and compositions thereof.

Group II, claims 11-15 and 96-101, drawn to nucleic acids encoding variant PDGFRA polypeptides, cells comprising said polynucleotides, and oligonucleotides that bind said nucleic acids.

Group III, claims 71-78, drawn to a method of detecting a condition by detecting a polynucleotide encoding a variant PDGFRA polypeptide in a sample.

Group IV, claims 79-83 and 88, drawn to a method of detecting a condition by detecting a variant PDGFRA polypeptide in a sample.

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Group V, claims 84-87, 89-95, 105 and 106, drawn to agents or compounds (including antibodies) that bind variant PDGFRA, and kits comprising said agents.

Group VI, claims 102-104, drawn to a method of screening comprising determining if a test compound binds to or interacts with a variant PDGFRA polypeptide.

**Note:** Claims 63-70 are linking claims that link Inventions III and IV (see below). According to Office practice, the linking claims are not listed with the above groups.

The inventions listed as Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking groups I-VI appears to be that they all relate to a genus of PDGFRA polypeptides encompassed by claim 1. The prior art teaches the following embodiments encompassed by this genus:

(1) Claim 1 encompasses a PDGFRA polypeptide "comprising an amino acid sequence as set forth in SEQ ID NO: 27". U.S. Patent 5,686,572 (published 11/11/97) teaches a PDGFRA sequence of SEQ ID NO: 4. An alignment instant SEQ ID NO: 27 and SEQ ID NO: 4 of the '572 patent is attached to this Office Action as Sequence Alignment #1. This alignment reveals the two sequences are identical except at residues 560-564, 566-571 and 841-848. However, the sequence of SEQ ID NO: 27 indicates that each of positions 560-564, 566-571 or 841-848 are represented by an "Xaa". The "misc features" for the sequence indicate that each "Xaa" represents one of several amino acids. For each position, the amino acid shown in SEQ ID NO: 4 of the '572 patent is represented as one of the amino acids encompassed by "Xaa". More specifically, SEQ ID NO: 27 indicates that the "Xaa" for each of positions 560-564, 566-571 and 842-847 represents any of the 20 natural amino acids; that the "Xaa" for position 841 includes "Arg" as found at position 841 of SEQ ID NO: 4 of the '572 patent; and that "Xaa" for position 848 includes "Asn" as found at position 848 of SEQ ID NO: 4 of the '572 patent. As such, the genus of proteins that comprise SEQ ID NO: 27 (As encompassed by claim 1) include the specific sequence of SEQ ID NO: 4 of the '572 patent.

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(2) Claim 1 also encompasses a PDGFRA polypeptide comprising a fragment of SEQ ID NO: 27 comprising at least 10 contiguous amino acids including at least one variant amino acid site set forth in one or more of positions 560-571 or 841-848 of SEQ ID NO: 27. The specification clearly indicates that mutated proteins include those with deletions (see pg 9, line 3-11). Furthermore, dependent claim 9 is directed to a species in which the only variation with respect to wild type PDGFRA is a deletion of residues 560-564 (see Table 3 on pg 54 of the specification). Furthermore, claim 63 recites, "wherein the activating mutation comprises a variant nucleic acid sequence shown in one or more of positions 2072 through 2107 or 2090 through 2937 of SEQ ID NO: 26". Page 220 of the paper copy of the Sequence Listing filed on 12/10/2004 indicates that with respect to residues 2072-2086, "Any N may equal either no nucleotide (i.e., a deletion) or any nucleotide (i.e., a, t, g or c)." Residues 2090-2107 and 2916-2937 have the same notation. Furthermore, the claim indicates that one or more of residues 2072-2107 or 2090-2937 can be variant. As these recited residues overlap, this indicates the claim encompasses variant comprising deletions of residues 2072-2937 of SEQ ID NO: 26 (which encodes SEQ ID NO: 27). In view of these teachings, the genus of variant PDGFRA proteins of the invention encompasses proteins comprising fragments of SEQ ID NO: 27 (of at least 10 contiguous amino acids) in which one or more of residues 560-571 or 841-848 have been mutated, including deletion mutations.

Omura et al (1997. Journal of Biological Chemistry. 19: 12676-12682; cited on the 9/4/06 IDS) teaches a variant PDGFRA protein that is encompassed by claim 1. As shown above, SEQ ID NO: 27 is identical to the prior art PDGFRA sequence at residues 1-559. Omura teaches a truncated PDGFRA protein wherein "a *Bgl*III site (AGATCT) was introduced into the sequence encoding the juxtamembrane portion (amino acids 560-561) of the  $\alpha$ -receptor and used to ligate to the vector encoding three tandem HA epitopes followed by a stop codon". While the codon "AGA" codes for "Arg" as in the wildtype PDGFRA protein; the codon "TCT" codes for "Ser" instead of "Val". Therefore, the PDGFRA protein taught by Omura is variant at position 561. Furthermore, the triple HA epitope consists of 24 amino acids (i.e., the sequence repeated three times YPYDVPDYA). Therefore, the protein taught by Omura is also variant at residues 562-

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564 and 566-571. Finally, the protein taught by Omura ends after the triple HA epitope. Therefore, the protein taught by Omura is also variant at residues 841-848 (i.e., each of these residues is deleted, which as described above, is encompassed by the invention). As such, Omura teaches a PDGFRA polypeptide that is a fragment of SEQ ID NO: 27 comprising at least 10 contiguous amino acids including at least one variant amino acid as set forth in one or more positions 560 through 571 or 841 through 848 of SEQ ID NO: 27.

In summary, the prior art teaches two different embodiments of the PDGFRA encompassed by claim 1, which falls within Group I. Since the first claimed invention does not have a special technical feature, it follows that it does not share a special technical feature with the other claimed inventions. Therefore, the technical feature linking the inventions of group I-VI does not constitute a special technical feature as defined by PCT rule 13.2, as it does not define a contribution over the prior art.

### ***Linking Claims***

Claims 63-70 link(s) inventions III and IV. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 63-70. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

***Election of Species***

This application contains claims directed to the following patentably distinct species variant PDGFRA polypeptide:

- (1) SEQ ID NO: 4 (PDGFRA D842V), encoded by SEQ ID NO: 3;
- (2) SEQ ID NO: 6 (PDGFRA DIMH842-845), encoded by SEQ ID NO: 5;
- (3) SEQ ID NO: 8 (PDGFRA HSDN845-848P), encoded by SEQ ID NO: 7;
- (4) SEQ ID NO: 10 (PDGFRA ER561-562), encoded by SEQ ID NO: 9;
- (5) SEQ ID NO: 12 (PDGFRA SPDGHE566-571R), encoded by SEQ ID NO: 11;
- (6) SEQ ID NO: 21 (PDGFRA V561D), encoded by SEQ ID NO: 20;
- (7) SEQ ID NO: 23 (PDGFRA RVIES560-564), encoded by SEQ ID NO: 22; and
- (8) SEQ ID NO: 25 (PDGFRA RD841-842KI), encoded by SEQ ID NO: 24.

The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 11, 12, 14, 15, 63, 65-73, 75, 76, 79-81, 83-86, 89, 90, 92-99 and 101-106 are generic. Claims 2, 13, 64, 74, 77, 78, 82, 87, 88, 91, 100 and 107 recite each of the species as part of a Markush-type group.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species, including any claims subsequently added. An argument that a**

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claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.



### ***Rejoinder***

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

***Advisory Information***

Applicant is advised that the final rules on claims and continuations were published in the Federal Register on Tuesday, August 21, 2007. As of November 1, 2007, the claims in each application may not exceed 5 independent claims or 25 total claims absent the applicant assisting the examination process through the filing of an Examination Support Document (ESD). The following is taken from the published rules package:

- **Applicants may present, without an ESD, up to Five (5) independent claims or Twenty-five (25) total claims in an application.**
- **Applicant may present more than 5/25 claims, if applicant files an ESD before the first Office action on the merits (FAOM).**
- **The 5/25 claim threshold does not count withdrawn claims.**
  - **Applicant may provide a suggested restriction requirement (SRR) before first Office action or a restriction requirement.**
- **The 5/25 claim threshold does count all of the claims present in other copending application(s) having a patentably indistinct claim, but not the claims in issued patents.**
  - **Applicant may present up to 15/75 claims via an initial application and 2 continuation or CIP applications prosecuted serially.**

**The final rules will become effective November 1, 2007, and will apply to all pending applications as of that date.** Applicants are advised to ensure that the elected claims are compliant with the new rules to avoid delay of prosecution. There will be no change to the examiner practice prior to the date the rules become effective.

Information on the new rules will be available at:

<http://www.uspto.gov/web/offices/pac/dapp/opla/presentation/clmcontfinalrule.html>

Guidelines for ESD under 37 CFR 1.265 will be available at:

<http://www.uspto.gov/web/offices/pac/dapp/opla/presentation/esdguidelines090607.pdf>

If Applicant has questions concerning the new rules, email [patentpractice@uspto.gov](mailto:patentpractice@uspto.gov) or call 571-272-7704.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary C. Howard whose telephone number is 571-272-2877. The examiner can normally be reached on M-F 9:30 AM - 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

zch

/Elizabeth C. Kemmerer/

Primary Examiner, Art Unit 1646

SEQUENCE  
ALIGNMENT  
#1

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<!--StartFragment-->RESULT 1
US-08-168-917-4
; Sequence 4, Application US/08168917
; Patent No. 5686572
; GENERAL INFORMATION:
; APPLICANT: Wolf, David
; APPLICANT: Tomlinson, James E.
; APPLICANT: Fretto, Larry J.
; APPLICANT: Giese, Neill A.
; APPLICANT: Escobedo, Jaime A.
; APPLICANT: Williams, Lewis T.
; TITLE OF INVENTION: DOMAINS OF EXTRACELLULAR REGION OF HUMAN
; TITLE OF INVENTION: PLATELET-DERIVED GROWTH FACTOR RECEPTOR POLYPEPTIDES
; NUMBER OF SEQUENCES: 23
; CORRESPONDENCE ADDRESS:
; ADDRESSEE: TOWNSEND and TOWNSEND
; STREET: Steuart Street Tower, 20th Floor \ One Market
; STREET: Plaza
; CITY: San Francisco
; STATE: California
; COUNTRY: US
; ZIP: 94105
; COMPUTER READABLE FORM:
; MEDIUM TYPE: Floppy disk
; COMPUTER: IBM PC compatible
; OPERATING SYSTEM: PC-DOS/MS-DOS
; SOFTWARE: PatentIn Release #1.0, Version #1.25
; CURRENT APPLICATION DATA:
; APPLICATION NUMBER: US/08/168,917
; FILING DATE:
; CLASSIFICATION: 435
; PRIOR APPLICATION DATA:
; APPLICATION NUMBER: US/07/650,793
; FILING DATE:
; ATTORNEY/AGENT INFORMATION:
; NAME: Ching, Edwin P.
; REGISTRATION NUMBER: 34,090
; REFERENCE/DOCKET NUMBER: 12418-14
; TELECOMMUNICATION INFORMATION:
; TELEPHONE: (415) 326-2400
; TELEFAX: (415) 326-2422
; INFORMATION FOR SEQ ID NO: 4:
; SEQUENCE CHARACTERISTICS:
; LENGTH: 1089 amino acids
; TYPE: amino acid
; TOPOLOGY: linear
; MOLECULE TYPE: protein
US-08-168-917-4

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Query Match 99.7%; Score 5533; DB 1; Length 1089;  
 Best Local Similarity 98.3%; Pred. No. 0;  
 Matches 1070; Conservative 0; Mismatches 19; Indels 0; Gaps 0;

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